Supreme Court, U.S.
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No. _____

In The

Supreme Court of the United States

October Term, 1994

SUBBY MARTELLO,

Petitioner,

vs.

CIBA VISION CORPORATION,
A Georgia Corporation,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Eighth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Did the Circuit Court err when it held that federal regulation of class III Medical devices, despite an absence of a specific regulation or guideline, preempted state common law?

PARTIES INVOLVED IN THE PROCEEDINGS BELOW

SUBBY MARTELLO, Plaintiff, and

CIBA VISION CORPORATION, A Georgia Corporation, Defendant.

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D. REFERENCE TO OFFICIAL AND UNOFFICIAL REPORTS OF DECISIONS

The opinion in this case was officially reported as *Martello v. Ciba Vision Corporation,* 42 F.3d 1167 (8th Cir. 1994).

E. GROUNDS OF JURISDICTION

1. The original opinion was entered on December 12, 1994.

2. Appellants motion for rehearing was denied on February 7, 1995.

3. Jurisdiction of this Court is invoked pursuant to 28 USC Sec. 1254(1).

F. STATUTES AND PROVISIONS INVOLVED

Due to the length of the provisions involved in this case, only the citations thereto are included herein with the full text included in the appendix.

21 USC § 360c
21 USC § 360e
21 USC § 360k

21 CFR § 814.20
21 CFR § 808
21 CFR § 808.1
21 CFR § 860.7
21 CFR § 886.5928

G. STATEMENT OF THE CASE

The Plaintiff suffered an infection and was blinded in one eye after using the Defendant's soft contact lens cleaning system. The blindness of the Plaintiff was alleged to have resulted from his use of the system and this action alleging strict liability, breach of warranty and negligence claims against the Defendant was instituted.

The Defendant moved for, and was granted, summary judgment on the basis of preemption of Plaintiff's state law claims by the Medical Device Amendments of 1976. Because the Defendant's product was a Class III device under that act, it was subjected to strenuous premarketing testing and review by a panel of FDA experts. The District Court held, and the 8th Circuit agreed, that approval by the FDA of a Class III Medical device preempts state law claims arising from that device's manufacture. The Courts held that Section 360K preempts the claims of the Plaintiff.

The Appellant argued below and reasserts here that the Courts which have held that the MDA preempts common law claims are wrong, their holdings are in direct conflict with prior holdings of this Court, and allow federal preemption to occur when no specific statute or regulation requires it. There is no regulation setting forth the safety standards to be applied to a contact lens system. Rather the only effective regulations are those requiring FDA approval of the device. Under these circumstances, the Appellant submits no preemption exists.

ARGUMENT

The rationale of the courts below was that the requirements of 21 U.S.C. Section 360k preempted the plaintiff's common law causes of action. 21 U.S.C. Sections 360c et seq., contain the Medical Device Amendments of 1976 to the Federal Food, Drug & Cosmetics Act. Those amendments made medical devices subject to regulation by the FDA. When the amendments were passed, Congress passed a specific federal preemption section relating to medical devices. That section, contained at 21 U.S.C. Section 360k is set forth above.

The reasoning of the Eighth Circuit in the court below was consistent with the reasoning of other circuits that have considered this question. See *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993) cert. denied ___ U.S. ___, 114 S.Ct. 84, 126 L.Ed.2d 52 (1993) and *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993) cert. denied ___ U.S. ___, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993).

Each of the above cases have held that preemption occurs because, when dealing with a Class III medical device, the intent of the Federal Government was that the demands placed upon the manufacturer of such a device preempt any state law claims regarding the safety or manufacture of the device. This is true, even though there is no specific regulation in the MDA setting forth the requirements for a Class III medical device.

> "Dupont argued that, regardless of the absence of specific provisions regarding PPFE, the basic statutory framework of the MDA requiring all medical devices to be registered, classified and approved by the FDA, 21 U.S.C. Section 360,

> establishes the necessary requirements to pre-empt state law. The MDA divides medical devices into three classes. . . . Class III devices present a potential unreasonable risk of illness or injury and thus require premarket approval, a stringent process requiring the manufacturer to submit detailed information to an FDA panel of experts. *Id*, at 1419. . . .
>
> *Because of the more extensive requirements imposed on Class III devices, the MDA preempts state law regarding a Class III device, even if the only MDA regulation specifically addressing the device is an identification regulation. . . . " Anguiano v. E. I. Du Pont De Nemours & Company, Inc.*, 44 F.3d 806, 810 (9th Cir. 1995).

Thus, what the Court is dealing with in the MDA cases is a federal regulatory scheme which, instead of enacting safety standards by regulation or rule instead attempts to delegate the responsibility for making such regulations to a panel of experts who then approves or disapproves of a device based upon unpublished standards and without public input. The Courts have, in contravention of this Court's analysis of federal preemption, given this panel of expert's opinions the force of federal law and preempted state common law in the field.

Pursuant to the provisions of that Act, the Department of Health and Human Services enacted regulations dealing with the federal preemption section. Those regulations directly applicable to the issue at bar are found at 21 CFR Section 808.1, and are set forth fully herein.

The cases of *Cippollone v. Liggett Group, Inc.*, 505 U.S. ___, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) and *CSX Transportation, Inc. v. Easterwood*, ___ U.S. ___, 113 S.Ct. 1732, 123 L.Ed.2d 387 (1993), are of primary importance to the issue.

In *Cippollone*, this Court held that a provision of the Public Health Cigarette Smoking Act of 1965 requiring cigarette manufacturers to place a warning on their packaging, but further holding that no other statements may be required on any cigarette package, did not preempt common law claims against cigarette manufacturers based on products liability and failure to warn.

This Court held that, because preemption matters must be decided narrowly and with the understanding that preemption is not a favored doctrine, that the 1965 Act only preempted state and federal rule making bodies from mandating particular cautionary statements and did not pre-empt state law damage actions.

The Court went on to hold that a 1969 amendment to the Act which barred the imposition of any requirements or prohibitions under state law. The Court held that the proper analysis was to narrowly, but fairly, construe the federal law and compare it with the legal duty that is the predicate of the common law damages action and see whether that action was specifically preempted by the statute. 112 S.Ct. 2621.

Cippollone contains several points favorable to the appellant:

1) The preemption clause considered in *Cippollone* was broad, all encompassing, and contained no reservation of rights to the states or regulation of cigarette promotion, packaging and advertising;

2) Despite the broad preemptive statutory language considered in *Cippollone*, the Supreme Court still held that claims of plaintiffs based upon fraudulent misrepresentations; breach of implied warranty; and other common law claims not specifically addressed by the Act were *not* preempted by federal law; and

3) The Supreme Court rejected the theory of the Court of Appeals that the preemption clause contained in the statute was to be read broadly. Rather, the Supreme Court employed a narrow construction of the statute consistent with its previous law that claims of preemption were to be narrowly construed.

The Supreme Court in *Cippollone* held that specific areas regulated under the Act were preempted, while other theories against cigarette manufacturers not specifically mentioned in the Act or regulations, were not preempted.

Thus, *Cippollone* can be read to demonstrate a legitimate hostility to any theory of preemption that goes beyond the necessary literal interpretation of federal statutes, regulations and rules.

In the case of *CSX Transportation, Inc. v. Easterwood*, ___ U.S. ___, 113 S.Ct. 1732, 123 L.Ed.2d 387 (1993), this Court considered the issues of preemption in regard to application of the Federal Railroad Safety Act. That Act (like the Food & Drug Act involved in this case) has both

an explicit preemption clause *and* an explicit savings clause.

The Court noted that the different circuits had adopted conflicting standards of review of claims of preemption relating to the Railroad Safety Act. (113 S.Ct. 1732, 1734, n.1) The Court, in determining the standard to be applied, stated:

> Where a state statute conflicts with or frustrates federal law, the former must give way . . . In the interest of avoiding unintended encroachment on the authority of the states, however, a court interpreting a federal statute pertaining to a subject traditionally governed by state law will be reluctant to find preemption. Thus, preemption will not lie unless it is the 'clear and manifest purpose of Congress.' . . . Evidence of preemptive purpose is sought in the text and structure of the statute at issue . . . If the statute contains an express preemption clause, the test of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." 113 S.Ct. 132, 137.

The Court in *CSX* then went on to note that the preemption clause of the statute was bracketed by an express saving clause. The Court noted that the preemption language displayed "considerable solicitude for state law." 113 S.Ct. 1732, 1738.

The Court in *CSX* then went on to a detailed analysis of the regulations issued by the Secretary of Transportation in compliance with the Act. It was the analysis of the

Court that the regulations, in and of themselves, determined the extent of regulation by the federal government and thus determined the extent of preemption assumed by the federal government.

CSX is important for the following reason:

1. It emphasizes that the amount of preemption, if any, incurred as a result of a federal statute, depends upon the express wording of that statute;

2. It demonstrates that when Congress has indicated a solicitude for a state law, that solicitude should be utilized in the analysis of the statute; and

3. It indicates the overriding importance of the language of the federal regulations involved in the case.

A review of the requirements of the Act show clearly that the contact lens cleaner manufactured by the defendant in this case is, essentially, unregulated by the FDA. While approval of the FDA is necessary prior to marketing of the device, no substantive regulations exist dictating design standards, standards of manufacture, warnings, labels, warranties, remedies, or any other related matters. The only requirement is that the company get advance approval to market the device. There are *no* regulations in effect which have been published determining what these standards are.

If the FDA published regulations specifically stating what the design of the machines were, what materials could be used in them, how they were to be manufactured, how they were to be labeled, what warnings were to be put on them, and similar matters, the plaintiff concedes that preemption would apply. However, the

FDA has not done this. The appellant has been unable to find *any* regulation explicitly dealing with any of the issues involved in this case. By the language of the Act, and the interpretation of the government under the Act, as set forth in the regulations governing preemption, the common law theories of negligence, strict liability, and breach of warranty, are not "different from" or "in addition to" "requirements applicable under this chapter."

Because no federal regulation or statute has set safety standards for the contact lens cleaners in this case, federal preemption should not have been found. Nevertheless, the various courts of appeals of this Country have adopted a rule of law that state common law rules of negligence, implied warranty and strict liability do not apply in the cases of Class III medical devices. They have done so in contravention of this Court's rulings in *Cippollone* and *CSX*. Certiorari should be granted to consider whether the circuit courts of appeals have misinterpreted this Court's intention in those cases and have misapplied the law to the detriment of both the plaintiffs who have been injured and to the various States whose common law and regulations have been deemed preempted.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 94-1206NE

Subby Martello, Appellant, v. Ciba Vision Corporation, A Georgia Corporation, Appellee.	*	Appeal from the United States District Court for the District of Nebraska.

Submitted: October 14, 1994

Filed: December 12, 1994

Before FAGG, Circuit Judge, ROSS, Senior Circuit Judge, and MAGILL, Circuit Judge.

FAGG, Circuit Judge.

Subby Martello developed a corneal infection and lost vision in one eye after using CIBA AOSEPT Catalytic Disinfection System (AOSEPT), a soft contact lens disinfection system manufactured by Ciba Vision Corporation. Alleging AOSEPT caused his loss, Martello brought this products liability action against Ciba Vision raising state tort claims of strict liability, breach of express and implied warranties, and negligence related to AOSEPT's design, inspection, instructions, labelling, warning, and

testing. The district court granted summary judgment to Ciba Vision, holding Martello's claims are expressly preempted by the Medical Device Amendments Act of 1976 (MDA), 21 U.S.C. §§ 360c-360k (1988 & Supp. V 1993). Martello appeals and we affirm.

The MDA gives the Food and Drug Administration (FDA) authority over medical devices and authorizes the FDA to issue implementing regulations. Under the MDA, medical device manufacturers must register each device with the FDA before beginning manufacture. *See* 21 U.S.C. § 360c. After registration, the FDA classifies each device according to the level of regulatory control necessary to provide for the device's safety and effectiveness. *See id.* Because Class I devices present the least risk of harm, they are the most loosely regulated and are subjected only to general controls. *Id.* § 360c(a)(1)(A). Class II devices, including artificial knee joints and tampons, are more heavily regulated and are subject to special controls. *Id.* § 360c(a)(1)(B). Class III devices, like artificial heart valves and contact lens solutions, are the most heavily regulated and must pass premarket approval. *Id.* § 360c(a)(1) (C). To obtain premarket approval, the manufacturer must submit detailed information about the device's testing, design, components, performance standards, manufacturing, packaging, and labelling. *See id.* § 360e(c)(1); 21 C.F.R. § 814.20 (1994). After a panel of experts reviews the application, 21 U.S.C. § 360e(c)(2), the FDA may approve the device for sale if valid scientific evidence reasonably assures the device's safety and effectiveness, *see id.* § 360c(a)(2); 21 C.F.R. § 860.7. When a device has been approved for sale, the manufacturer must

maintain certain records and continue to report to the FDA about the device. 21 U.S.C. § 360i.

The district court held Martello's claims were expressly preempted under the MDA's preemption provision, 21 U.S.C. § 360k(a). Under § 360k(a), a state cannot establish a requirement that relates to a device's safety or effectiveness and that differs from, or adds to, any MDA requirement applicable to the device. The FDA has interpreted § 360k(a) as preempting any state requirement, "whether established by statute, ordinance, regulation, or court decision." 21 C.F.R. § 808.1(b). Thus, the MDA's preemptive effect extends to state tort actions. *National Bank of Commerce v. Kimberly-Clark Corp.*, No. 93-3012, 1994 WL 580798, at *2 (8th Cir. Oct. 25, 1994); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *Lamontagne v. E.I. Du Pont de Nemours & Co.*, 834 F. Supp. 576, 582 (D. Conn. 1993) (citing cases). In a regulation interpreting § 360k(a), the FDA has indicated, "State . . . requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the [MDA] . . . making any existing divergent [s]tate . . . requirements applicable to the device different from, or in addition to, the specific [FDA] requirements." 21 C.F.R. § 808.1(d). Put another way, "[P]reemption does not apply when the FDA has issued no regulations or other requirements specific to the particular device." *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993). The FDA's regulations interpreting § 360k(a) are controlling. *See id.* Thus, a state tort claim is preempted only if (1) the FDA has established regulations specific to the medical

device in issue, (2) the state claim imposes a requirement different from, or in addition to, any FDA requirement for the device, and (3) the claim relates to the safety or effectiveness of the device, or to any other matter included in an MDA requirement for the device. *Lamontagne*, 834 F. Supp. at 583.

Martello concedes AOSEPT is a Class III medical device under the MDA. *See* 21 C.F.R. § 886.5928 (defining soft contact lens solution as a device intended to clean, disinfect, wet, or store a soft contact lens, and assigning Class III). Martello also concedes the FDA had approved Ciba Vision's premarket application for AOSEPT before Martello used the product. Nevertheless, Martello contends his claims are not preempted because the regulations contain no specific requirements for soft contact lens disinfection systems. We disagree.

The premarket approval process is a specific requirement for a device within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d). *Stamps*, 984 F.2d at 1421-22; *Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 760-61 (S.D.N.Y. 1994); *see also Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir.) (MDA's procedural requirements have same preemptive effect as substantive requirements), *cert. denied*, 113 S. Ct. 327 (1992). The MDA thus expressly preempts state tort claims involving the safety and effectiveness of Class III devices when the claims would impose additional requirements in areas regulated through the premarket approval process. *Stamps*, 984 F.2d at 1421-22; *King*, 983 F.2d at 1134; *Brown v. Medtronic, Inc.*, 852 F. Supp. 717, 719-20 (S.D. Ind. 1994) (citing cases). Under this rule, courts have held the MDA preempts state law claims of

strict liability, breach of express and implied warranties, misrepresentation, failure to warn, and negligence in design, manufacturing, and labelling of Class III devices because the claims involve areas regulated through the premarket application process. *Stamps*, 984 F.2d at 1421-22; *King*, 983 F.2d at 1134.

FDA approval of a premarket application shows the FDA has reviewed a device's testing, design specifications, intended use, manufacturing method, performance standard, and labelling, *see* 21 U.S.C. § 360e(c)(1), and decided the device is safe and effective, *see id.* § 360c(a)(2). Here, all of Martello's state tort claims deal directly with AOSEPT's safety and effectiveness and would add requirements in areas reviewed in the premarket approval process. Martello did not claim the AOSEPT he used did not comply with federal regulations, *see Reiter v. Zimmer, Inc.*, 830 F. Supp. 199, 204 (S.D.N.Y. 1993), or that the AOSEPT he used was contaminated, *see King*, 983 F.2d at 1135 (21 U.S.C. § 360k(a) does not preempt contaminated device claim); *Slater*, 961 F.2d at 1334 (same); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 19 (1st Cir. 1994) (explaining contaminated device claim); 21 C.F.R. § 808.1(d)(6)(ii).

Because Martello's claims are expressly preempted under the MDA, we affirm the district court's grant of summary judgment to Ciba Vision.

A true copy.

Attest:

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT.

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 94-1206NEO

Subby Martello, Appellant, v. Ciba Vision Corporation, A Georgia Corporation, Appellee.	*	Appeal from the United States District Court for the District of Nebraska

JUDGMENT

(Filed Feb. 17, 1995)

This appeal from the United States District Court was submitted on the record of the district court, briefs of the parties and was argued by counsel.

After consideration, it is hereby ordered and adjudged that the judgment of the district court in this cause is affirmed in accordance with the opinion of this Court.

December 12, 1994

A true copy.

ATTEST: Michael E. Gans

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEBRASKA

SUBBY MARTELLO, Plaintiff, v. CIBA VISION CORPORATION, a Georgia corporation, Defendant.	8:CV91-00121 ORDER AND JUDGMENT (Filed Dec. 21, 1993)

Pursuant to the memorandum opinion entered herein this date,

IT IS ORDERED that defendant's motion for summary judgment (Filing No. 72) is granted. Plaintiff's complaint is dismissed.

DATED this 21st day of December, 1993.

BY THE COURT:

/s/ Lyle E. Strom
LYLE E. STROM, Chief Judge
United States District Court

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEBRASKA

SUBBY MARTELLO, Plaintiff, v. CIBA VISION CORPORATION, a Georgia corporation, Defendant.	)	8:CV91-00121 MEMORANDUM OPINION (Filed Dec. 21, 1993)

This matter is before the Court on defendant's motion for summary judgment filed pursuant to Fed. R. Civ. P. 56(c). (Filing No. 72). The Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1332(a) and 1441(a).

I.

To succeed in this motion, defendant must show that no genuine issue of material fact exists, and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). For purposes of summary judgment, "genuine" refers to whether the material issue has any real basis on the record. *Hartnagel v. Norman*, 953 F.2d 394, 395 (8th Cir. 1992) (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986)). "Material" refers to whether the genuine issue of fact could "affect the outcome of the suit." *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Upon review of a motion for summary judgment, the Court must give the party

opposing the motion the benefit of all favorable inferences. *Holloway v. Lockhart*, 813 F.2d 874, 878 (8th Cir. 1987).

II.

On January 31, 1991, plaintiff filed a petition in the District Court of Douglas County, Nebraska. On March 4, 1991, defendant removed the case to this Court. In his complaint, plaintiff alleges that defendant's contact lens disinfectant system, Ciba AOSEPT Catalytic Disinfection System ("AOSEPT"), caused him to develop an eye infection, acanthamoeba corneal infection, which eventually resulted in a near complete vision loss in his right eye and severe shock to the nervous system. Plaintiff asserts theories of recovery based on strict liability, negligence, and breach of express and implied warranties.

Defendant bases its summary judgment motion primarily on the doctrine of preemption. Specifically, defendant argues that the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c through 360k, expressly preempt plaintiff's state law tort claims.

In 1976, Congress amended the Food, Drug and Cosmetic Act to bring "medical devices" within the jurisdiction of the Food and Drug Administration (FDA). Medical Device Amendments of 1976, 21 U.S.C. §§ 360c – 360k. The amendments are designed to protect the public from hazardous medical devices by empowering the FDA to set national safety standards. *See* 1976 U.S. Code Cong. & Admin. News at pp. 1070, 1071. In the regulations promulgated pursuant to these amendments, soft contact lens disinfectant solutions, such as AOSEPT, are classified

as Class III medical devices. 21 C.F.R. § 886.5928. Class III devices are required to undergo premarket approval ("PMA"), the purpose of which is to "provide reasonable assurance of [the device's] safety and effectiveness." 21 U.S.C. §360c(a)(1)(C). To obtain PMA, the manufacturer must submit all information bearing on the safety and effectiveness of the device, as well as any proposed labeling to the Secretary. 21 U.S.C. § 360e(c)(1). Based on the information submitted, the FDA must approve or deny application for PMA. 21 U.S.C. § 360e(d)(2).

The contact lens solution which is the subject of this case has completed the PMA procedure for class III medical devices. On June 10, 1982, the FDA informed the defendant that the initial review of the defendant's PMA application was complete and that the application was suitable for filing. The letter stated that the application would next undergo a scientific and compliance review. (Dennis Aff. Filing No. 73, ¶ 2, Ex. 1). On March 17, 1983, the FDA approved the defendant's PMA application for the disinfection system, for use in disinfecting SOFTCON contact lenses. (Dennis Aff. ¶ 3, Filing No. 73, Ex. 2). On April 8, 1983, the FDA announced this approval in the Federal Register. 48 Fed. Reg. 15,327-15,328 (April 8, 1983). On December 23, 1983, the FDA approved the defendant's disinfection system for use in disinfecting all types of contact lenses. (Dennis Aff. ¶ 5, Filing No. 73, Ex. 4). Thus, in 1987, when the plaintiff used the defendant's contact lens disinfecting solution, the solution was classified as a class III medical device.

III.

It is a familiar and well-established principle that the Supremacy Clause of the United States Constitution invalidates state laws that "interfere with, or are contrary to," federal law. *Hillsborough County v. Automated Medical Labs., Inc.*, 471 U.S. 707, 712 (1985) (quoting *Gibbons v. Ogden*, 9 Wheat. 1, 211 (1824) (Marshall, C.J.)). In general, state laws are preempted if they actually conflict with an express or implied federal declaration, or if the state law effects an area that is so pervasively controlled by federal law that no room is left for state rulemaking. *See Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 143 (1982); *See also Karl v. Burlington Northern R. Co.*, 880 F.2d 68, 77 (8th Cir. 1989).

In the interest of avoiding unintended encroachment on the authority of the States, courts have been generally reluctant to find a federal statute preempts state or local requirements which pertain to an area of the law "traditionally governed by state law." *CSX Transp., Inc. v. Easterwood*, 113 S.Ct. 1732, 1737, 123 L. Ed. 2d 387, 396 (1993). In such cases, courts will not find preemption unless it is "the clear and manifest purpose of Congress." *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Thus, because state law traditionally governs matters related to health and safety, *Hillsborough*, 471 U.S. at 715, the Court must "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *CSX Transp., Inc.*, 113 S. Ct. at 1737, 123 L. Ed. 2d at 396.

In the present case, the amendments contain a provision expressly addressing their intended preemptive scope:

> Except as provided in subsection (b) of this section [which is inapplicable to this case], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Pursuant to this statute, which applies to state and local requirements "established by statute, ordinance, regulation, or court decision," 21 C.F.R. § 808.1(b), a state may not establish a requirement that relates to the safety and effectiveness of a device which is different from or in addition to those requirements found in the MDA. The Court must therefore determine (1) whether federal regulations or statutes

exist which set forth requirements which pertain to contact lens solution;[1] (2) whether the state law claims asserted in plaintiff's complaint create requirements which are in addition to or different from the federal requirements; and (3) whether the state law relates to the safety or effectiveness of the contact solution or to "any other matter included in a requirement" which applies to the solution under the MDA. 21 U.S.C. § 360k(a); *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744, 751 (M.D. Pa. 1992).

In this case, the relevant requirements that are applicable to contact lens solution, in addition to the PMA process itself, are set forth in 21 C.F.R. §§ 800.10 and 800.12. These sections outline the requirements for contact lens solution sterility, and tamper-resistant packaging and labeling. The regulation dealing with contact lens

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[1] In making such a determination, the Court is mindful that the regulatory language accompanying the statute makes it clear that "[t]he FDA did not intend to preempt all state laws and regulations pertaining to [contact lens disinfectant solutions]." *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 244 (5th Cir. 1989). Section 801.1(d) provides that, "[s]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . . . " 21 C.F.R. § 801(d). Courts have interpreted the statutory and regulatory language to limit the scope of preemption "to instances where there are specific FDA requirements applicable to a particular device or class of devices. . . . The phrase 'or in addition to any requirements applicable under this Act to the device' means that an FDA requirement must exist before preemption can occur." *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475, 478 (S.D. Ind. 1988) (*quoting* 43 Fed. Reg. 18,662 (1978)).

sterility states the solution should be sterile and "of such purity and quality as to be suitable for safe use in the eye." 21 C.F.R. § 800.10(a)(1). This section also details the packaging requirements to protect the sterility of the solution and the warning requirements for minimizing "the hazard of injury resulting from contamination during use." 21 C.F.R. § 800.10(c). The regulation dealing with tamper resistant packaging and labeling details the standard packaging for such solutions and the labeling requirements for notifying the public of such packaging. 21 C.F.R. §§ 800.12(b) and 800.12(c). Clearly these sections set forth requirements which pertain to contact lens solution, thereby fulfilling the first condition of preemption.

The second and third conditions of preemption, that the state law creates a requirement which relates to the safety and effectiveness of the solution and which adds to or is different from the federal requirements, are also satisfied. In his complaint, plaintiff asserts a strict liability claim based on defective design and manufacturing of the contact lens solution. Plaintiff also claims defendant was negligent in several respects, including negligent design, production and manufacturing, failure to properly inspect, and failure to adequately label. Finally, plaintiff asserts that defendant breached express and implied warranties. Although no case law exists which directly address this issue with respect to these particular sections, the Court finds the regulations are sufficiently broad in scope to apply to the allegations in plaintiff's complaint.

Essentially, plaintiff asserts claims similar to those in *Covey v. Surgidev Corp.*, 815 F. Supp. 1089 (N.D. Ohio 1993). In *Covey*, the plaintiff asserted that the defendant

manufacturer was "liable strictly for negligence for its faulty design of lens, its failure to warn consumers, and its inadequate testing of the device." *Id.* at 1095. In dismissing the complaint, the court stated that "[s]uch claims, which deal directly with the safety and effectiveness of the device, are clearly preempted because they would require practices different from those imposed under the regulations." *Id.* Likewise, in this case, plaintiff's negligence, strict liability, and warranty claims directly deal with the safety and effectiveness of the solution and also would require practices different from, or in addition to, those imposed by the regulations. Therefore, the plaintiff's claims are preempted.

The Court's conclusion in this case is also supported by several cases which address the preemptive scope of section 360k as it relates to other Class III medical devices. In the great majority of those cases, the courts have found that section 360k preempts state requirements which relate to health and safety. For Example, in *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir.), 114 S. Ct. 86, 126 L. Ed. 2d 54 (1993), the Fifth Circuit interpreted the language of section 360k to preempt a state tort cause of action if it "(1) constitutes a requirement different from, or in addition to, any requirement the MDA makes applicable to the device at issue and (2) relates either to (a) the safety or effectiveness of the device or (b) any other matter included in a requirement made applicable to the device by the MDA." In applying this test to the Class III anti-wrinkle cream in *Stamps*, the Court held that the state tort causes of action asserted in that case were preempted because they constituted requirements that

were "either different from or in addition to, a requirement – the Class III PMA process – that the MDA has made applicable to" the anti-wrinkle cream, and because the state law claims "undoubtedly" related to "either the safety or effectiveness of zyderm and zyplast, or to some other matter included in the PMA requirements applicable to the products." *Id.* at 1422. *See also King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84, 126 L. Ed. 2d 52 (holding plaintiff's state common law causes of action against collagen manufacturer based on failure to warn, strict liability, breach of express and implied warranty, negligence, product misbranding, misrepresentation failure to warn, and fraud were all preempted because allowing such claims would impose additional or different requirements from the MDA); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327, 121 L. Ed. 2d 245 (1992) (holding that the MDA preempted plaintiff's causes of action against intraocular lens manufacturer based on negligence, strict liability, and breach of implied warranty).

This case is not one where plaintiff alleges defendant failed to comply with its own FDA regulations. *Reiter v. Zimmer, Inc.*, 830 F. Supp. 199, 203 (S.D.N.Y. 1993). Nor is it a case where the FDA has failed to issue regulations which relate to the particular device in question. *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246 (5th Cir. 1989). Rather, this case is one where plaintiff asserts causes of action which relate to the safety or effectiveness of Class III medical device and which would force defendant to act different from the requirements imposed by the federal regulations. Clearly these type of requirements are

exactly the kind Congress intended to preempt. Therefore, defendant's motion will be granted. A separate order in accordance with this memorandum opinion will be entered herein.

DATED this 21st day of December, 1993.

BY THE COURT:

/s/ Lyle E. Strom
LYLE E. STROM, Chief Judge
United States District Court

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 94-1206NEO

Subby Martello, Appellant, v. Ciba Vision Corporation, A Georgia Corporation, Appellee.	*	Appeal from the United States District Court for the District of Nebraska

(Filed Jan. 9, 1995)

Appellant's motion for extension of time to file petition for rehearing has been considered by the Court and is granted. Appellant may have to 1/17/95 to file the petition for rehearing.

January 5, 1995

Order entered at the Direction of The Court

/s/ Michael E. Gans

Clerk, U.S. Court of Appeals, Eighth Circuit

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT
U.S. COURT & CUSTOM HOUSE
1114 MARKET STREET
ST. LOUIS, MISSOURI 63101

MICHAEL E. GANS
Clerk of Court

TELEPHONE
(314) 539-3600

February 7, 1995

Mr. John P. Inserra
INSERRA LAW OFFICES
Sunset Valley Law Building
2580 S. 90th Street
Omaha, NE 68124

RE: 94-1206NEO Subby Martello vs. Ciba Vision Corp.

Deal Counsel:

Enclosed is a copy of an order entered today in the above case at the direction of the court.

Sincerely,

/s/ Michael E. Gans
Michael E. Gans
Clerk of Court

mam

Enclosure(s)

cc: Hon. Lyle E. Strom
William J. Brennan Jr.
Gerald L. Friedrichsen
James Welsh

District Court/Agency Case Number(s):
8:CV91-00121

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 94-1206NEO

Subby Martello, Appellant, v. CIBA Vision Corporation, A Georgia Corporation, Appellee.	*	Appeal from the United States District Court for the District of Nebraska (Filed Feb. 7, 1994)

The petition for rehearing filed by the appellant has been considered by the court and is denied.

February 7, 1995

Order Entered at the Direction of the Court:

/s/ Michael E. Gans
Clerk, U.S. Court of Appeals, Eighth Circuit

21 U.S.C. Section 360k:

"(a) Except as provided in subsection (b), . . . no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement –

'(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.'"

21 USCA 360c Classification of devices intended for human use

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) Class I, General Controls

(i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it –

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) Class II, Special Controls

A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) Class III, Premarket Approval

A device which because –

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that

the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined –

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 360d and 360e of this title, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) –

(i) which is sufficient to determine the effectiveness of a device, and

(ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 360d and 360e of this title, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

(b) Classification panels

(1) For purposes of –

(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices (other than devices classified by subsection (f) of this section) into the classes established by subsection (a) of this section. For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before May 28, 1976, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related

professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day so engaged, including travel time; and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of Title 5, for persons in the Government service employed intermittently.

(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

(c) Classification panel organization and operation

(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use

are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) of this section for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 360d or 360e of this title to a device recommended to be classified in class II or class III.

(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 360, 360i, or 360j(f) of this title.

(C) In the case of a device which has been referred under paragraph (1) to a panel, and which –

(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and

(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or

(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976.

(d) Panel recommendation; publication; priorities

(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit

comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 360, 360i, or 360j(f) of this title shall not apply to the device. A regulation which makes a requirement of section 360, 360i, or 360j(f) of this title inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

(B) A device described in subsection (c) (2) (C) of this section shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

(3) In the case of devices classified in class II and devices classified under this subsection in class III and described in section 360e(b) (1) of this title the Secretary may establish priorities which, in his discretion, shall be used in applying sections 360d and 360e of this title, as appropriate, to such devices.

(e) Classification changes

(1) Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device's classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect under section 360d or 360e of this title with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) of this section a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 360d of this title for such device.

(2) By regulation promulgated under paragraph (1), the Secretary may change the classification of a device from class III –

(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

(f) Initial classification and reclassification of certain devices

(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless –

(A) the device –

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b) of this section, or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) classifying the device in class I or II.

(2)(A) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a

petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition.

(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary may for good cause shown refer the petition to an appropriate panel established or authorized to be used under subsection (b) of this section. A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

(ii) The requirements of paragraphs (1) and (2) of subsection (c) of this section (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 360, 360i, and 360j(f) of this title) shall apply with respect to

consideration by panels of petitions submitted under subparagraph (A).

(C)(i) Within ninety days from the date the Secretary receives the recommendation of a panel respecting a petition (but not later than 210 days after the filing of such petition) the Secretary shall by order deny or approve the petition. If the Secretary approves the petition, the Secretary shall order the classification of the device into class I or class II in accordance with the criteria prescribed by subsection (a) (1) (A) or (a) (1) (B) of this section. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order approving such petition shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

(ii) The requirements of paragraphs (1) and (2) (A) of subsection (d) of this section (relating to publication of recommendations, opportunity for submission of comments, and exemption from sections 360, 360i, and 360j(f) of this title) shall apply with respect to action by the Secretary on petitions submitted under subparagraph (A).

(3) If a manufacturer reports to the Secretary under section 360(k) of this title that a device is substantially equivalent to another device –

(A) which the Secretary has classified as a class III device under subsection (b) of this section,

(B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and

(C) for which no final regulation requiring premarket approval has been promulgated under section 360e(b) of this title,

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 360(k) of this title a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 360(k) report is being made and which has not been submitted to the Secretary under section 360i of this title. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

(g) Information

Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this chapter, the Secretary shall provide such person a written statement of the

classification (if any) of such device and the requirements of this chapter applicable to the device.

(h) Definitions

For purposes of this section and sections 351, 360, 360d, 360e, 360f, 360i, and 360j of this title

(1) a reference to "general controls" is a reference to the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title,

(2) a reference to "class I", "class II", or "class III" is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a) (1) of this section, and

(3) a reference to a "panel under section 360c of this title" is a reference to a panel established or authorized to be used under this section.

(i) Substantial equivalence

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(l) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device –

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information,

including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 360(k) of this title respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

21 USCA 360e :

(a) General requirement

A class III device –

(1) which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval.

(b) Regulation to require premarket approval

(1) In the case of a class III device which –

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rule making. Such notice shall contain –

(i) the proposed regulation;

(ii) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

(iii) opportunity for the submission of comments on the proposed regulation and the proposed findings; and

(iv) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(B) If, within fifteen days after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classification of a device, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 360c of this title, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 360c(e) of this title.

(3) After the expiration of the period for comment on a proposed regulation and proposed findings published under paragraph (2) and after consideration of comments submitted on such proposed regulation and findings, the Secretary shall (A) promulgate such regulation and publish in the Federal Register findings on the matters referred to in paragraph (2) (A) (ii), or (B) publish a notice terminating the proceeding for the promulgation

of the regulation together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(4) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation amend or revoke any regulation promulgated under this subsection. A regulation to amend or revoke a regulation under this subsection shall be promulgated in accordance with the requirements prescribed by this subsection for the promulgation of the regulation to be amended or revoked.

(c) Application for premarket approval

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain –

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

(2) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary –

(A) may on the Secretary's own initiative, or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application

which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 360c of this title,

refer such application to the appropriate panel under section 360c of this title for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

(d) Action on application for premarket approval

(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) of this section (except as provided in section 360j(l) (3) (D) (ii) of this title or unless, in accordance with subparagraph (B) (i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall –

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

(B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to a regulation promulgated under subsection (b) of this

section unless he finds that the continued availability of the device is necessary for the public health.

(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 360j(e) of this title.

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that –

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 360j(f) of this title;

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(E) such device is not shown to conform in all respects to a performance standard in effect under section

360d of this title compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

(3) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section, and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g) of this section, of an order of the Secretary approving an application.

(e) Withdrawal and temporary suspension of approval of application for premarket approval

(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 360c of this title, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds –

(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 360i(a) of this title, (ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title, or (iii) has not complied with the requirements of section 360 of this title;

(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 360j(f) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 360d of this title compliance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard.

(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section.

(3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed

expeditiously under paragraph (1) to withdraw such application.

(f) Product development protocol

(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c) of this section, such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, he shall refer the proposed protocol to the appropriate panel under section 360c of this title for its recommendation respecting approval of the protocol.

(3) A proposed product development protocol for a device may be approved only if –

(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c) of this section; and

(B) the Secretary determines that the proposed protocol provides –

(i) a description of the device and the changes which may be made in the device,

(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and, when relevant, packing and installation of the device,

(v) an identifying reference to any performance standard under section 360d of this title to be applicable to any aspect of such device,

(vi) if appropriate, specimens of the labeling proposed to be used for such device,

(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 360c of this title, may require, and

(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under

paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of Title 5.

(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion –

(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c) (1) of this section.

(6)(A) The Secretary may, after providing the person who has an approved protocol an opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that –

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds –

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion

which has become effective as provided in subparagraph (B) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e) (1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

(8) A person who has an approved protocol subject to an order issued under paragraph (6) (A) revoking such protocol, a person who has an approved protocol with respect to which an order under paragraph (6) (B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section.

(g) Review

(1) Upon petition for review of –

(A) an order under subsection (d) of this section approving or denying approval of an application or an order under subsection (e) of this section withdrawing approval of an application, or

(B) an order under subsection (f) (6) (A) of this section revoking an approved protocol, under subsection (f) (6) (B) of this section declaring that an approved

protocol has not been completed, or under subsection (f) (7) of this section revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of Title 5, on the order. The panel or panels which considered the application, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2)(A) Upon petition for review of –

(i) an order under subsection (d) of this section approving or denying approval of an application or an order under subsection (e) of this section withdrawing approval of an application, or

(ii) an order under subsection (f) (6) (A) of this section revoking an approved protocol, under subsection (f) (6) (B) of this section declaring that an approved protocol has not been completed, or under subsection (f) (7) of this section revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

(B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent for grade GS-18 of the General Schedule for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member

may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of Title 5 for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

(h) Service of orders

Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

(i) Revision

(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under

paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 360i of this title. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(2) After the issuance of an order under paragraph (1) but before December 1, 1995, the Secretary shall publish a regulation in the Federal Register for each device –

(A) which the Secretary has classified as a class III device, and

(B) for which no final regulation has been promulgated under subsection (b) of this section,

revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 360c(a) of this title. Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this paragraph and provide reasonable opportunity for the submission of comments on any such regulation. No regulation requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from

the date of its publication in the Federal Register as a proposed regulation.

(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the regulation requiring a device to remain in class III, establish a schedule for the promulgation of a regulation under subsection (b) of this section for each device which is subject to the regulation requiring the device to remain in class III.

21 CFR § 814.20 Application.

(a) The applicant or an authorized representative shall sign the PMA. If the applicant does not reside or have a place of business within the United States, the PMA shall be countersigned by an authorized representative residing or maintaining a place of business in the United States and shall identify the representative's name and address.

(b) Unless the applicant justifies an omission in accordance with paragraph (d) of this section, a PMA shall include:

(1) The name and address of the applicant.

(2) A table of contents that specifies the volume and page number for each item referred to in the table. A PMA shall include separate sections on nonclinical laboratory studies and on clinical investigations involving human subjects. A PMA shall be submitted in six copies each bound in one or more numbered volumes of reasonable size. The applicant shall include information that it believes to be trade secret or confidential commercial or

financial information in all copies of the PMA and identify in at least one copy the information that it believes to be trade secret or confidential commercial or financial information.

(3) A summary in sufficient detail that the reader may gain a general understanding of the data and information in the application. The summary shall contain the following information:

(i) Indications for use. A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

(ii) Device description. An explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device. A brief description of the manufacturing process should be included if it will significantly enhance the reader's understanding of the device. The generic name of the device as well as any proprietary name or trade name should be included.

(iii) Alternative practices and procedures. A description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.

(iv) Marketing history. A brief description of the foreign and U.S. marketing history, if any, of the device, including a list of all countries in which the device has been marketed and a list of all countries in which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device.

The description shall include the history of the marketing of the device by the applicant and, if known, the history of the marketing of the device by any other person.

(v) Summary of studies. An abstract of any information or report described in the PMA under paragraph (b)(8)(ii) of this section and a summary of the results of technical data submitted under paragraph (b)(6) of this section. Such summary shall include a description of the objective of the study, a description of the experimental design of the study, a brief description of how the data were collected and analyzed, and a brief description of the results, whether positive, negative, or inconclusive. This section shall include the following:

(A) A summary of the nonclinical laboratory studies submitted in the application;

(B) A summary of the clinical investigations involving human subjects submitted in the application including a discussion of subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate (any investigation conducted under an IDE shall be identified as such).

(vi) Conclusions drawn from the studies. A discussion demonstrating that the data and information in the application constitute valid scientific evidence within the meaning of § 860.7 and provide reasonable assurance that the device is safe and effective for its intended use. A

concluding discussion shall present benefit and risk considerations related to the device including a discussion of any adverse effects of the device on health and any proposed additional studies or surveillance the applicant intends to conduct following approval of the PMA.

(4) A complete description of:

(i) The device, including pictorial representations;

(ii) Each of the functional components or ingredients of the device if the device consists of more than one physical component or ingredient;

(iii) The properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition;

(iv) The principles of operation of the device; and

(v) The methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device.

(5) Reference to any performance standard under section 514 of the act or the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b et seq.) in effect or proposed at the time of the submission and to any voluntary standard that is relevant to any aspect of the safety or effectiveness of the device and that is known to or that should reasonably be known to the applicant. The applicant shall –

(i) Provide adequate information to demonstrate how the device meets, or justify any deviation from, any performance standard established under section 514 of the act or under the Radiation Control for Health and Safety Act, and

(ii) Explain any deviation from a voluntary standard.

(6) The following technical sections which shall contain data and information in sufficient detail to permit FDA to determine whether to approve or deny approval of the application:

(i) A section containing results of the nonclinical laboratory studies with the device including microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests as appropriate. Information on nonclinical laboratory studies shall include a statement that each such study was conducted in compliance with Part 58, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(ii) A section containing results of the clinical investigations involving human subjects with the device including clinical protocols, number of investigators and subjects per investigator, subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, tabulations of data from all individual subject report forms and copies of such forms for each subject who died during a clinical investigation or

who did not complete the investigation, results of statistical analyses of the clinical investigations, device failures and replacements, contraindications and precautions for use of the device, and any other appropriate information from the clinical investigations. Any investigation conducted under an IDE shall be identified as such. Information on clinical investigations involving human subjects shall include the following:

(A) A statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in Part 56, or was not subject to the regulations under § 56.104 or § 56.105, and that it was conducted in compliance with the informed consent regulations in Part 50; or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(B) A statement that each study was conducted in compliance with Part 812 or Part 813 concerning sponsors of clinical investigations and clinical investigators, or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(7) For a PMA supported solely by data from one investigation, a justification showing that data and other information from a single investigator are sufficient to demonstrate the safety and effectiveness of the device and to ensure reproducibility of test results.

(8)(i) A bibliography of all published reports not submitted under paragraph (b)(6) of this section, whether

adverse or supportive, known to or that should reasonably be known to the applicant and that concern the safety or effectiveness of the device.

(ii) An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any source, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience.

(iii) Copies of such published reports or unpublished information in the possession of or reasonably obtainable by the applicant if an FDA advisory committee or FDA requests.

(9) One or more samples of the device and its components, if requested by FDA. If it is impractical to submit a requested sample of the device, the applicant shall name the location at which FDA may examine and test one or more devices.

(10) Copies of all proposed labeling for the device. Such labeling may include, e.g., instructions for installation and any information, literature, or advertising that constitutes labeling under section 201(m) of the act.

(11) An environmental assessment under § 25.22(a)(18) prepared in the applicable format in § 25.31, unless the action qualifies for exclusion under § 25.24(e)(4) or (5). If the applicant believes that the action qualifies for exclusion, the PMA shall under § 25.23(c) provide information that establishes to FDA's satisfaction that the

action requested is included within the excluded category and meets the criteria for the applicable exclusion.

(12) Such other information as FDA may request. If necessary, FDA will obtain the concurrence of the appropriate FDA advisory committee before requesting additional information.

(c) Pertinent information in FDA files specifically referred to by an applicant may be incorporated into a PMA by reference. Information in a master file or other information submitted to FDA by a person other than the applicant will not be considered part of a PMA unless such reference is authorized in writing by the person who submitted the information or the master file. If a master file is not referenced within 5 years after the date that it is submitted to FDA, FDA will return the master file to the person who submitted it.

(d) If the applicant believes that certain information required under paragraph (b) of this section to be in a PMA is not applicable to the device that is the subject of the PMA, and omits any such information from its PMA, the applicant shall submit a statement that identifies the omitted information and justifies the omission. The statement shall be submitted as a separate section in the PMA and identified in the table of contents. If the justification for the omission is not accepted by the agency, FDA will so notify the applicant.

(e) The applicant shall periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device or that

may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling. The update report shall be consistent with the data reporting provisions of the protocol. The applicant shall submit three copies of any update report and shall include in the report the number assigned by FDA to the PMA. These updates are considered to be amendments to the PMA. The time frame for review of a PMA will not be extended due to the submission of an update report unless the update is a major amendment under § 814.37(c)(1). The applicant shall submit these reports –

(1) 3 months after the filing date,

(2) Following receipt of an approvable letter, and

(3) At any other time as requested by FDA.

(f) If a color additive subject to section 721 of the act is used in or on the device and has not previously been listed for such use, then, in lieu of submitting a color additive petition under Part 71, at the option of the applicant, the information required to be submitted under Part 71 may be submitted as part of the PMA. When submitted as part of the PMA, the information shall be submitted in three copies each bound in one or more numbered volumes of reasonable size. A PMA for a device that contains a color additive that is subject to section 721 of the act will not be approved until the color additive is listed for use in or on the device.

(g) FDA has issued a PMA guideline to assist the applicant in the arrangement and content of a PMA. This guideline is available from the Center for Devices and Radiological Health, Office of Standards and Regulations

(HFZ-80), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(h) A PMA, PMA amendment, PMA supplement, or correspondence with respect to a PMA shall be sent to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850.

21 CFR § 860.7 Determination of safety and effectiveness.

(a) The classification panels, in reviewing evidence concerning the safety and effectiveness of a device and in preparing advice to the Commissioner, and the Commissioner, in making determinations concerning the safety and effectiveness of a device, will apply the rules in this section.

(b) In determining the safety and effectiveness of a device for purposes of classification, establishment of performance standards for class II devices, and premarket approval of class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors:

(1) The persons for whose use the device is represented or intended;

(2) The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

(3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

(4) The reliability of the device.

(c)(1) Although the manufacturer may submit any form of evidence to the Food and Drug Administration in an attempt to substantiate the safety and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.

(2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness.

Such information may be considered, however, in identifying a device the safety and effectiveness of which is questionable.

(d)(1) There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

(2) Among the types of evidence that may be required, when appropriate, to determine that there is reasonable assurance that a device is safe are investigations using laboratory animals, investigations involving human subjects, and nonclinical investigations including in vitro studies.

(e)(1) There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

(2) The valid scientific evidence used to determine the effectiveness of a device shall consist principally of well-controlled investigations, as defined in paragraph (f) of this section, unless the Commissioner authorizes

reliance upon other valid scientific evidence which the Commissioner has determined is sufficient evidence from which to determine the effectiveness of a device, even in the absence of well-controlled investigations. The Commissioner may make such a determination where the requirement of well-controlled investigations in paragraph (f) of this section is not reasonably applicable to the device.

(f) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of a well-controlled clinical investigation. They provide the basis for the Commissioner's determination whether there is reasonable assurance that a device is effective based upon well-controlled investigations and are also useful in assessing the weight to be given to other valid scientific evidence permitted under this section.

(1) The plan or protocol for the study and the report of the results of a well-controlled investigation shall include the following:

(i) A clear statement of the objectives of the study;

(ii) A method of selection of the subjects that:

(a) Provides adequate assurance that the subjects are suitable for the purposes of the study, provides diagnostic criteria of the condition to be treated or diagnosed, provides confirmatory laboratory tests where appropriate and, in the case of a device to prevent a disease or condition, provides evidence of susceptibility and exposure to the condition against which prophylaxis is desired;

(b) Assigns the subjects to test groups, if used, in such a way as to minimize any possible bias;

(c) Assures comparability between test groups and any control groups of pertinent variables such as sex, severity or duration of the disease, and use of therapy other than the test device;

(iii) An explanation of the methods of observation and recording of results utilized, including the variables measured, quantitation, assessment of any subject's response, and steps taken to minimize any possible bias of subjects and observers;

(iv) A comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be specified and an explanation provided of the methods employed to minimize any possible bias of the observers and analysts of the data. Level and methods of "blinding," if appropriate and used, are to be documented. Generally, four types of comparisons are recognized:

(a) No treatments. Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated patients;

(b) Placebo control. Where there may be a placebo effect with the use of a device, comparison of the results of use of the device with an ineffective device used under conditions designed to resemble the conditions of use under investigation as far as possible;

(c) Active treatment control. Where an effective regimen of therapy may be used for comparison, e.g., the condition being treated is such that the use of a placebo or the withholding of treatment would be inappropriate or contrary to the interest of the patient;

(d) Historical control. In certain circumstances, such as those involving diseases with high and predictable mortality or signs and symptoms of predictable duration or severity, or in the case of prophylaxis where morbidity is predictable, the results of use of the device may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable patients or populations who received no treatment or who followed an established effective regimen (therapeutic, diagnostic, prophylactic).

(v) A summary of the methods of analysis and an evaluation of the data derived from the study, including any appropriate statistical methods utilized.

(2) To insure the reliability of the results of an investigation, a well-controlled investigation shall involve the use of a test device that is standardized in its composition or design and performance.

(g)(1) It is the responsibility of each manufacturer and importer of a device to assure that adequate, valid scientific evidence exists, and to furnish such evidence to the Food and Drug Administration to provide reasonable assurance that the device is safe and effective for its intended uses and conditions of use. The failure of a manufacturer or importer of a device to present to the Food and Drug Administration adequate, valid scientific

evidence showing that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone, or by general controls and performance standards, may support a determination that the device be classified into class III.

(2) The Commissioner may require that a manufacturer, importer, or distributor make reports or provide other information bearing on the classification of a device and indicating whether there is reasonable assurance of the safety and effectiveness of the device or whether it is adulterated or misbranded under the act.

(3) A requirement for a report or other information under this paragraph will comply with section 519 of the act. Accordingly, the requirement will state the reason or purpose for such request; will describe the required report or information as clearly as possible; will not be imposed on a manufacturer, importer, or distributor of a classified device that has been exempted from such a requirement in accordance with § 860.95; will prescribe the time for compliance with the requirement; and will prescribe the form and manner in which the report or information is to be provided.

(4) Required information that has been submitted previously to the Center for Devices and Radiological Health need not be resubmitted, but may be incorporated by reference.

21 CFR § 808.1 Scope

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption

from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the

practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of

adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by

or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

21 CFR § 886.5928 Soft (hydrophilic) contact lens solution.

(a) Identification. A soft (hydrophilic) contact lens solution is a device intended to clean, disinfect, wet, or store a soft (hydrophilic) contact lens (s 886.5925).

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

21 CFR Section 808:

"(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

* * *

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they

are not 'requirements applicable to a device' within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

'(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced

by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.' "

Supreme Court, U.S.
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(2)

No. 94-1832

In The

Supreme Court of the United States

October Term, 1994

SUBBY MARTELLO,

Petitioner,

v.

CIBA VISION CORPORATION,
A Georgia Corporation,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Eighth Circuit

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Medical Device Amendments of 1976 – which expressly preempt state requirements relating to safety or effectiveness that are different from or in addition to federal requirements – bar state tort claims against the manufacturer of a Class III medical device whose use, labelling, manufacturing, sterilization, packaging and performance met the specific requirements imposed by the Food and Drug Administration as conditions of premarket approval?

CORPORATE AFFILIATES

Pursuant to Rule 29.1, the following is a list of all parent companies and subsidiaries of respondent CIBA Vision Corporation: Ciba-Geigy Corporation and CIBA Vision Group Management, Inc.

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STATEMENT OF THE CASE

Petitioner, Subby Martello, filed this action in state court alleging AOSEPT®, a contact lens disinfectant solution, allowed him to develop an eye infection which eventually resulted in a near-complete loss of vision in his right eye. Plaintiff's petition contained one cause of action asserting theories of recovery based on strict liability; negligence, including failure to warn; and breach of express and implied warranties.

After CIBA Vision removed the case to federal court, it filed a motion for summary judgment. Because AOSEPT® is a Class III medical device, CIBA Vision contended petitioner's claims were preempted by 21 U.S.C. § 360k of the Medical Device Amendments Act of 1976. That statute preempts state law claims that relate to the safety or effectiveness of a medical device and establish a requirement that is different from or adds to any requirement made applicable to the device by the Medical Device Amendments Act. The United States District Court for the District of Nebraska, the Honorable Lyle E. Strom, granted CIBA Vision's motion for summary judgment. The court ruled plaintiff's claims were preempted by 21 U.S.C. § 360k. The Eighth Circuit Court of Appeals affirmed. *Martello v. CIBA Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994).

THE FEDERAL REGULATORY SCHEME PERTAINING TO MEDICAL DEVICES AND ITS APPLICATION TO CONTACT LENS SOLUTIONS.

The Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360l, gave the United States Food and

Drug Administration ("FDA") wide-ranging authority over medical devices. The amendments were enacted "to assure that medical devices . . . meet the requirements of safety and effectiveness before they are put in widespread use throughout the United States." S.Rep. No. 33, 94th Cong., 15 Sess. 2 (1975) *Reprinted in 1976* U.S. Code & Cong. News 1070, 1071.

The MDA established a three-tier system of device classification based upon the degree of regulation the FDA deems necessary for assurances of safety and effectiveness. 21 U.S.C. § 360c; 21 C.F.R. § 860.3(c). Class I devices generally do not present an unreasonable risk of injury, and are subject only to "general controls" relating to manufacture of the devices. *See* 21 U.S.C. § 360c(a)(1)(A). Class II devices, because of complexity in design or use, present a higher potential of risk of injury and may be subject to more strict regulation in the form of specific "performance standards." *See* 21 U.S.C. § 360c(a)(1)(B).

Class III devices – the most thoroughly regulated category – require premarket approval (PMA) by the FDA. The purpose of the PMA process is "to provide reasonable assurance of [the device's] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). A device falls within class III if: (1) there is insufficient information to allow it to be classified as Class I or II; and (2) the device is to support or sustain human life, or "for a use which is of substantial importance in preventing impairment of human health . . . ;" or (3) it "presents a potential unreasonable risk of illness or injury." 21 U.S.C. §§ 360c(a)(1)(C)(i), (ii)(I), (II). Class III medical devices

cannot be sold to the public until they are approved by the FDA.

The PMA process for a Class III device is quite extensive. The procedure requires that the manufacturer submit to the FDA a detailed application on the device's design, intended use, components, properties and the principles of its operation; its manufacturing methods, packaging and its performance standards, if any; samples of the device; samples of the proposed labeling; and any other information deemed relevant by the FDA before marketing the product. The manufacturer must also submit all reasonably known scientific information bearing on the safety and effectiveness of the device. 21 U.S.C. § 360e(c); 21 C.F.R. § 814.20.

Each PMA application is then referred by the FDA to a panel of experts. 21 U.S.C. § 360e(c)(2). The FDA may either approve the device for sale or return the application for additional information or testing. 21 U.S.C. § 360e(d). Approval is granted if the FDA finds that there is a "reasonable assurance" that the device is "safe and effective," "weighing and probable benefit to health from the device against any probable risk of illness or injury from such use." 21 U.S.C. § 360c(a)(2); 21 C.F.R. § 860.7.

Once a Class III device has been approved for sale, it may not be manufactured, purchased, stored, labeled, distributed or advertised in a manner inconsistent with any conditions of approval specified in the PMA order approving the device. 21 C.F.R. § 814.80. In addition, the manufacturer must maintain certain records and report to the FDA regarding the device, particularly where the

manufacturer "becomes aware of information that reasonably suggests" that one of its devices "caused or contributed to a death . . . or serious injury," or malfunctioned in such a way likely to cause the same. 21 U.S.C. § 360i(1)(A), (B).

APPROVAL OF AOSEPT® AS A CLASS III MEDICAL DEVICE

CIBA Vision manufactures and distributes a contact lens disinfectant system called AOSEPT®, a medical device used to disinfect soft contact lenses. Soft contact lens disinfectant solutions are classified as Class III medical devices. 21 C.F.R. § 886.5928. As such, AOSEPT® had to undergo the premarket approval process under the MDA before it could be sold to the public.

AOSEPT® Catalytic Disinfection System was given premarket approval by the FDA under the name of SEPTICON® Disinfection Regimen ("SEPTICON®"). On July 29, 1982, the FDA approved for filing the Premarket Approval Application for SEPTICON®. On March 17, 1983, the FDA issued premarket approval for SEPTICON® for use in disinfecting SOFTCON® (Difacon A Contact Lenses) pursuant to FDA and applicable federal regulations. On April 8, 1983, the FDA published the announcement of its approval of SEPTICON® in the Federal Register, Volume 69, No. 69, pp. 15327-28. On December 23, 1983 the FDA issued premarket approval for SEPTICON® Disinfection Regimen for use with all soft, hydrophilic (contact lenses). On March 21, 1984, the FDA

was advised of a change in the product name from SEPTICON® Disinfection Regimen to AOSEPT® Catalytic Disinfection System. The PMA and corresponding FDA approvals for SEPTICON® Disinfection Regimen and AOSEPT® Disinfection System are owned by CIBA Vision Corporation. (Pet. App. 10.)

In addition to the normal PMA requirements, the FDA has specific regulations first promulgated in 1982 governing sterility and tamper-resistant packaging requirements of contact lens disinfectant solutions. 21 C.F.R. §§ 800.10, 800.12. Section 800.10 states that unsterile contact lens solution products are adulterated and potentially misbranded under the FDA. To reduce the risk of contamination of contact lens solutions, section 800.12 requires specific tamper-resistant packaging measures to be taken for contact lens solutions. It also specifies labeling which must accompany the product.

PROCEEDINGS BELOW

Petitioner conceded, as he does here, that AOSEPT® is a Class III medical device under the MDA. Petitioner also conceded, as he does here, that the FDA had approved the premarket application for AOSEPT® before he used it. Because AOSEPT® had been given premarket approval as a Class III medical device, CIBA Vision filed a motion for summary judgment in the district court. CIBA Vision argued all of the petitioner's state-law claims were expressly preempted by 21 U.S.C. § 360k(a).

In sustaining the motion, the district court analyzed petitioner's claims in accordance with this court's decisions in *CSX Transportation, Inc. v. Easterwood*, ___ U.S. ___, 113 S.Ct. 1732, 123 L.Ed.2d 387 (1993) and *Cipollone v. Liggett Group, Inc.*, 505 U.S. ___, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). The district court correctly focused on the language of 21 U.S.C. § 360k to determine whether the federal statute preempts state or local requirements which pertain to an area of law traditionally governed by state law. As required by *Cipollone*, he concluded 21 U.S.C. § 360k(a) preempts not only state statutes and regulations but also state common law claims because such actions impose "requirements" within the meaning of the statute.

The district court also noted the FDA's view, as expressed in the agency's regulations, that 21 U.S.C. § 360k(a) applies to any requirement having the force and effect of law, whether "established by statute, ordinance regulation or court decision." 21 C.F.R. § 808.1(b). The court then analyzed petitioner's claims and determined that his claims of strict liability, breach of warranty, negligence, and failure to warn were all predicated on the safety or effectiveness of AOSEPT® and would have imposed requirements different from or in addition to those imposed by the FDA and thus were expressly preempted.

The Eighth Circuit Court of Appeals affirmed. That court agreed a state tort claim is preempted only if (1) the FDA has established regulations specific to the medical device in issue, (2) the state claim imposes a requirement different from, or in addition to, any FDA requirement for the device, and (3) the claim relates to the safety or

effectiveness of the device, or to any other matter included in an MDA requirement for the device.

As he does here, petitioner contended his claims were not preempted because the FDA's regulations contained no specific requirements for soft contact lens disinfection systems. The Eighth Circuit disagreed. The court concluded the premarket approval process is a specific requirement for a Class III device within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d). The Eighth Circuit observed that FDA approval of a premarket application shows the FDA has reviewed a device's testing, design specifications, intended use, manufacturing method, performance standard and labelling, and decided the device is safe and effective. The court concluded the MDA expressly preempts state tort claims involving the safety and effectiveness of Class III medical device when the claims would impose additional requirements in areas governed by the premarket approval process. Because all of petitioner's state tort claims dealt directly with AOSEPT®'s safety and effectiveness and would add requirements in areas reviewed in the premarket approval process, the court concluded petitioner's claim was expressly preempted. It affirmed the district court's grant of summary judgment to CIBA Vision.

REASONS FOR DENYING THE PETITION

The decision of the Eighth Circuit Court of Appeals is correct. It does not conflict with the decisions of this Court or any other appellate court. The petition should therefore be denied.

The application of 21 U.S.C. § 360k to approved Class III medical devices such as AOSEPT® represents a straight-forward exercise in express preemption. There can be little doubt that 21 U.S.C. § 360k preempts state tort actions with respect to Class III devices that are subject to premarket approval requirements – nearly every court squarely to address the issue has so held. Including the Eighth Circuit in this case, four federal courts of appeal have now so held.

This Court denied certiorari after the Seventh Circuit ruled that 21 U.S.C. § 360k protects manufacturers of Class III devices from state tort claims that implicate requirements different from those imposed by the FDA. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir. 1992), *cert. denied*, ___ U.S. ___, 113 S.Ct. 327, 121 L.Ed.2d 246 (1992). This Court also denied certiorari in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *cert. denied*, ___ U.S. ___, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993) and *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993), *cert. denied*, ___ U.S. ___, 114 S.Ct. 84, 126 L.Ed.2d 52 (1993). In those decisions, the Fifth and First Circuit Courts of Appeal had ruled that state tort liability that would impose a requirement different from or in addition to the PMA process for Class III medical devices is pre-empted. *Accord Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994); *Talbott v. C.R. Bard*, 865 F.Supp. 37, 51 (D. Mass. 1994); *Brown v. Medtronic, Inc.*, 852 F.Supp. 717, 719-20 (S.D.Ind. 1994); *Bravman v. Baxter Healthcare Corp.*, 842 F.Supp. 747, 760-61 (S.D.N.Y. 1994); *Kemp v. Pfizer*, 835 F.Supp. 1015, 1020 (E.D. Mich. 1993); and *Covey v. Surgidev Corp.*, 815 F.Supp. 1089, 1095 (N.D. Ohio 1993).

Petitioner's argument that no federal regulation or statute has set safety standards for contact lens disinfectant solution rests on a fundamental misapprehension of the federal regulatory scheme for Class III medical devices as was extensively considered and rejected below. By 21 U.S.C. § 360k, Congress expressly preempted competing state requirements:

> "[N]o state or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act."

21 U.S.C. § 360k(a). In this case, petitioner's state law tort claim would erect "requirements" beyond those specifically established by the FDA and are therefore preempted.

Class III medical devices are subject to the most extensive level of federal regulation and to the most specific requirements governing all aspects of their design and labelling. The manufacturer must submit full information on these and other aspects to the FDA before marketing and commercial distribution can proceed. The approval represents a license to market the product in accordance with the precise conditions specified by the FDA to insure the safety and effectiveness of the device. *See* 21 U.S.C. § 360e. These conditions – which specify

how the particular device in question must be manufactured and labeled – are the "requirements" that cannot be supplanted by states under 21 U.S.C. § 360k. As the FDA itself has written, state requirements are preempted when the FDA has "established specific counterpart regulations or there are other specific requirements applicable to a particular device under the Act." 21 C.F.R. § 808.1(d).

The Eighth Circuit may have explained it best:

> "FDA approval of a premarket application shows the FDA has reviewed a device's testing, design specifications, intended use, manufacturing method, performance standard, and labelling, *see* 21 U.S.C. § 360e(c)(1), and decided the device is safe and effective, *see id.* § 360c(a)(2). Here, all of [petitioner's] state tort claims deal directly with AOSEPT®'s safety and effectiveness and would add requirements in areas reviewed in the premarket approval process."

42 F.3d, at 1169.

CONCLUSION

On the basis of the well-reasoned opinions of the courts below, as well as for the reasons stated in this brief, respondent CIBA Vision Corporation respectfully requests the petition be denied.

Respectfully submitted,

CIBA VISION CORPORATION,
Respondent,

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